HotDog Head Warming Wrap

Models B107

Instructions for Use

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CE
2460

INTRODUCTION

The HotDog Head Warming Wrap is a component of the HotDog Temperature Management System. These instructions apply to the following catalog number:

HotDog Product Description	Catalog Number	Quantity	
Head Warming Wrap	B107	1	CE 2460

A101 Cables are available separately.

INDICATIONS FOR USE

The HotDog Temperature Management System is intended to prevent or treat hypothermia and to provide warmth to patients. The System should be used in circumstances in which patients may not maintain a state of normothermia. The System can be used with adult and pediatric patients.

The System is intended primarily for use in hospitals and surgical centers including, without limitation, operating rooms, recovery rooms, emergency rooms, burn units, and on other medical/surgical floors.

TARGET PATIENT GROUP

The Head Warming Wrap is intended for use with adult patients in circumstances in which patients may not be able to maintain a state of normothermia.

INTENDED USE

The System is designed to compensate for body heat loss before, during, and after surgery, and in other situations in which patients may not be able to maintain a state of normothermia.

CONTRAINDICATIONS

- Do not warm ischemic or non-perfused tissue; thermal injury may result. Examples include tissue distal to aortic cross clamping, or when vasoconstrictive drugs would lead to severe, prolonged vasoconstriction.
- Do not warm patients receiving transdermal medication; increased drug delivery may occur.

WARNINGS

- Explosion Hazard – Do not use the HotDog Controller or Head Warming Wrap in the presence of flammable anesthetics or oxygen-enriched environments such as hyperbaric chambers, oxygen tents, etc.
- Do not place the heated area of the Head Warming Wrap under the patient.
- Inspect the Head Warming Wrap prior to use for signs of damage or excessive wear such as cuts, holes, or loose electrical connections. If signs of wear are evident, do not use the Head Warming Wrap until it is inspected by technical staff.
- Do not continue to use the HotDog Temperature Management System if the over-temperature indicator and/or alarm continue to sound after reset.
- The Head Warming Wrap is not sterile.

- California Proposition 65 Warning: The medical devices and products mentioned in this IFU may contain chemicals including Urethane or PVC, which is known to the State of California to cause cancer, birth defects, or other reproductive harm. For more information go to, www.p65warnings.ca.gov

CAUTION

Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare professional.

PRECAUTIONS

- Use under the direct supervision of a clinician.
- Monitor the patient's vital signs regularly during warming according to institutional protocol. If vital sign instability occurs, notify the clinician.
- Exercise caution when using multiple warming methods.
- Maintain contact between the patient and the labeled sensor on the Head Warming Wrap.
- Do not fold the Head Warming Wrap black-side to black-side during use, as localized hear build-up may occur in the overlapped area.
- Always use a barrier, such as a hair net, between the patient and the Head Warming Wrap.
- Adjust placement of the Head Warming Wrap during X-ray imaging as the white labeling and internal wiring located primarily along the edges of the Head Warming Wrap may appear in images.
- This device should not be disposed of with general waste at end of life. Follow local regulations for disposal. The device does not pose any potential hazard.
- Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the competent authority of the country in which it occurred.

INSTRUCTIONS FOR USE

1. Inspect the surface of the Head Warming Wrap for damage (e.g., cuts, holes, loose electrical connections). Do not use the Head Warming Wrap if it is damaged. Use only with HotDog controllers.
2. Place a suitable barrier (e.g. hair net on the patient) between the patient and the Head Warming Wrap.
3. Place the Head Warming Wrap around the patient's head, ensuring the heated portion of the Head Warming Wrap (black side) faces the patient.

   Warning: Do not place the heated area of the Head Warming Wrap under the patient.

4. Ensure patient is in contact with the Head Warming Wrap's temperature sensor. Indicated by the white target.
5. Route the securement strap underneath the patient's chin and attach to the button on the opposing end of the Head Warming Wrap.
6. Adjust the formable edge of the Head Warming Wrap to hold it in the correct position to ensure maximum contact with the patient. If there is extra Head Warming Wrap length, bend the formable edge to position the extra length on the patient's shoulders.
7. Insert one end of the A101 cable into the appropriate port on the HotDog Controller.

Controller Model	Port
WC0X	A
WC5X	A or B
WC71	A
WC77	A, B, C or D

8. Insert the other end of the A101 cable into the electrical connector on the Head Warming Wrap.
9. Turn the HotDog Controller on and select the desired temperature setting to begin warming. The time to reach the set-point temperature from 23 C +/-2 C is less than 10 minutes. If the Head Warming Wrap does not reach the selected temperature within 10 minutes an alarm will sound (Refer to the HotDog Controller User Manual.)
10. If the HotDog Controller alarm sounds when the Head Warming Wrap is connected, do not use the Head Warming Wrap until the alarm condition is resolved. (Refer to the "Alarms" section.)
11. At the conclusion of warming, remove the barrier and clean the Head Warming Wrap as necessary. (See "Care and Maintenance" section below.)

CARE AND MAINTENANCE

- Do not continue to use the Head Warming Wrap beyond the labeled expiration date, found on the cable.
- Do not launder or sterilize as this may damage the Head Warming Wrap.
- Do not immerse the Head Warming Wrap in liquids.
- Do not use high-level disinfectants (e.g. glutaraldehyde and peracetic acid) or hydrogen peroxide-based solutions to clean the Head Warming Wrap.
- Do not spray cleaning solutions into the electrical connector.
- Do not use cleaning or disinfection methods different from those recommended in the Instructions for Use without first checking with an authorized service representative to ensure that the proposed methods will not damage the equipment.
- Do not use the Head Warming Wrap if it shows signs of damage or excessive wear such as cuts, holes, or loose electrical connectors. Technical staff should perform inspection, such as electrical leakage and resistance testing, to determine if it is safe for use.
- Do not disassemble the Head Warming Wrap; the product contains no serviceable parts. If service is required, call an authorized service representative for assistance.

Storage

Store the Head Warming Wrap in a dry place, folded or on hanging hooks using the designated holes along the edges of the wrap. Do not allow the Head Warming Wrap to be cut or crushed. If folding is the preferred method of storage, please fold loosely and ideally not always in the same manner. Repetitive folding, especially if done so in a tight manner, may damage internal components and effect the product's longevity.

Cleaning—General

Clean and disinfect the Head Warming Wrap between patient uses if it appears visibly soiled. If the Warming Wrap is not visibly soiled, disinfection at the end of the operating day is recommended. Follow protocols for non-critical, non-sterile medical devices that may contact intact skin. Examples of similar devices include blood pressure cuffs, exam table covers, operating room table pads and surgical supports.

Hydrogen peroxide-based cleaning solutions should NOT be used because the vapors degrade the conductive fabric heaters.

In general, alcohol-based disinfectants are easiest to use since they are fast acting and can be sprayed or wiped on the wrap. Other cleaners that are compatible with the outer surfaces of the wrap include sodium hypochlorite (diluted bleach), phenolic germicidal detergent, and quaternary ammonium detergent. Iodine-containing cleaners may cause discoloration of the surface material and are therefore NOT recommended for routine cleaning. Dry thoroughly before use.

Caution: DO NOT place the Head Warming Wrap in an autoclave, sterilizer, automatic washer-disinfector or any other high temperature system as this may damage the product.

Cleaning & Disinfection Steps

The cleaning steps below are general recommendations and are not meant to replace hospital-specific cleaning protocols.

1. DO NOT allow cleaning fluids to get into the electrical connector.
2. If visible soiling is present, remove before applying a disinfectant. Scrub the affected area with detergent, using a soft brush or sponge to remove organic matter. Rinse the surface of the wrap using a dampened cloth. Do not immerse the wrap in liquids.
3. Apply a low or intermediate level disinfectant to the entire wrap by spraying or wiping. Follow the disinfectant manufacturer's application instructions.
4. Dry thoroughly before use.

ALARMS

All alarm conditions are classified as Medium Priority Technical Alarms. If an alarm occurs, unplug the device to reset the controller. Check the Head Warming Wrap and attempt to resolve the alarm. If Alarm Lights illuminate after a reset was performed, discontinue use and refer the system to Biomedical Engineering. Refer to Controller IFU for specific information on the Error Codes displayed.

DEFINITION OF SYMBOLS

	Attention, consult accompanying documents.		Natural Latex Free		BF Patient Applied Part according to IEC60601-1.
	Serial Number		Reference Number		Lot Number
	Manufacture Date		.Unique Device Identifier		Do not submerge.
	Temperature Sensor		Keep Dry		Conforms to European Medical Device Regulation 2017/745.
	Transport and Storage Humidity Range		Transport and Storage Temperature Range		Separate treatment from general waste at end of life. See Precautions for details.
	Not Sterile		Protect from sharp objects. Discontinue use if product is cut or damaged.		Do Not Place Under Patient
	Do not use after YYYY-MM-DD		Manufacturer		Medical Device restricted to sale by or on the order of a physician
	See IFU for Warnings		Medical Device		Consult the electronic instructions for use on the website at the URL provided.
	EU Authorized Representative		This side away from the patient		This side toward the patient
	MDR Importer				
IPX2	Protected against dripping water when tilted up to 15°; Vertically dripping water shall have no harmful effect when the enclosure is tilted at an angle up to 15° from its normal position. (The Controller)				
	Medical Equipment Classified by Intertek Testing Services NA Inc. with respect to electric shock, fire, and mechanical hazards only, in accordance with UL 60601-1. Classified under European Medical Device Regulation 2017/745 as a Class IIb device.				

HotDog is a trademark of Augustine Temperature Management, registered in the U.S. Patent & Trademark Office.

Devices are protected by some or all of the following patents: (US Patents 7,543,344; 7,714,255; 7,851,729; 7,786,408; 8,062,343; 8,283,602; 8,604,391; 8,624,164; 8,772,676; 8,986,359; 9,962,122; 9,668,303; 10,154,543; 10,201,935; 10,206,248; 10,506,668; PCT Patent EP 2,062,460) .Other patents are pending.

